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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,510	10/27/2003	Eugene M. Breznock		2672

7590 01/31/2007

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EXAMINER
HAND, MELANIE JO

ART UNIT	PAPER NUMBER
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/694,510	BREZNOCK ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-15,21-23,25,27 and 29-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-15,21-23,25,27 and 29-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 9-15, 21-23, 25, 27, 29-36 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9-11, 13-15, 21-23, 25, 27, 29-31 and 33-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Balbierz (U.S. Patent No. 6,770,070).

With respect to **claim 9:** Balbierz teaches a method of draining of fluid, air and contaminants from a thoracic cavity of a mammalian patient comprising: inserting a tapered tip 16' of a flexible trocar 12 and a distal end of an axially elongate tube 112 into an incision into a thoracic cavity of a mammalian patient, wherein the flexible trocar 12 is pre-inserted through a drainage lumen of a bidirectional, non-removable, pressure-operated valve 32 attached to a proximal end of the axially elongate tube 112 (Fig. 8) and through a drainage lumen 113 of the axially elongate tube 112 and extends substantially the length of the axially elongate tube 112 (Col. 11, lines 5-20,

Col. 12, lines 55-67); selectively bending a region near the distal tip of the axially elongate tube while advancing the axially elongate tube into the thoracic cavity, wherein the bending steers the axially elongate tube into the thoracic cavity during insertion (Col. 10, lines 35-42, 52-56); removing the flexible trocar 12 through the valve 32 from the drainage lumen 113 of the axially elongate tube 112 and the drainage lumen of the valve, as the trocar 12 serves as an introducer intended to be removed once the apparatus 10 is placed; and selectively opening or closing the valve 32 to control influx and efflux of fluid, air or contaminants into the thoracic cavity through the drainage lumen of the axially elongate tube. (Col. 12, lines 60-67)

With respect to **claim 10:** The bending of the axially elongate tube 112 is controlled from the proximal end of said axially elongate tube 112 whereby tortuous anatomy can be navigated. (Figs. 3a,3b, Col. 9, line 63 – Col. 10, line 15)

With respect to **claim 11:** The bending of said axially elongate tube 112 is caused by retraction of a control rod 25'. (Figs. 3a,3b, Col. 9, line 63 – Col. 10, line 15)

With respect to **claim 13:** The step of selectively bending a region near the distal tip of the axially elongate tube is replaced by the steps of: inserting a hollow needle 16 into the thoracic cavity (Col. 9, lines 44-49); inserting a guidewire 15 through the hollow needle 16 into the thoracic cavity (Col. 13, lines 1-15); removing the hollow needle 16 following placement of the guidewire 15; advancing the chest drainage tube 112, comprising a flexible trocar 12 further comprising a tapered distal tip 16' and a guidewire lumen extending within the trocar 12 for the length of the trocar 12 into the thoracic cavity over the guidewire 15 (Col. 9, lines 21-25); and removing the trocar 12, as the trocar 12 serves as an introducer intended to be removed once the apparatus 10 is placed.

With respect to **claim 14:** The chest drainage tube is pre-mounted to said trocar 12.

With respect to **claim 15:** The chest drainage tube 112 is subsequently fixed in position relative to the opening in the chest wall via closure device 52. (Col. 19, lines 14-19) Spring 52 clamps adjacent blood vessels or tissue together and thus also maintains chest drainage tube 112 in place.

With respect to **claim 21:** Balbierz teaches a method of draining of fluid, air and contaminants from a patient's thoracic cavity comprising: inserting a hollow needle 16 into an incision into the thoracic cavity of a patient; inserting a guidewire 15 through the hollow needle 16 into the thoracic cavity (Col. 13, lines 1-15); removing the hollow needle 16 after inserting the guidewire 15, as the needle 16 serves as an introducer intended to be removed once the apparatus is placed (Col. 11, lines 15-20); pre-attaching a non-removable, bidirectional valve 32, further comprising a drainage lumen and a valve control lumen, to the proximal end of an axially elongate tube 112, wherein the axially elongate tube comprises a proximal end, a distal end, and a drainage lumen 113 extending substantially the axial length of the axially elongate tube 112 (Col. 11, lines 15-20, Col. 12, lines 55-67, Col. 13, lines 1-15); inserting a flexible trocar 12 comprising a tapered distal tip 16', and a guidewire lumen extending the length of the flexible trocar 12, within the trocar 12, through a drainage lumen of the valve, into the proximal end of the axially elongate tube and into the drainage lumen of the axially elongate tube until the tapered distal tip 16' extends beyond the distal end of the axially elongate tube (Fig. 6A, Col. 9 , lines 21-24, Col. 12, lines 55-67); inserting a distal end of the axially elongate tube 112, comprising the pre-inserted flexible trocar 12 and pre-attached, pressure-operated, bidirectional

valve 32, over the guidewire 15 and through the incision into the thoracic cavity of the patient, wherein the distal end of the axially elongate tube 112 is advanced into the thoracic cavity of the patient (Fig. 4A, Col. 11, lines 15-20); removing the flexible trocar 12 from the drainage lumen 113 of the axially elongate tube 112 and from the drainage lumen of the valve 32, as the trocar 12 serves as an introducer intended to be removed once the apparatus 10 is placed; selectively opening or closing the drainage lumen of the valve 32, to control the influx and efflux of fluid, air or contaminants into the thoracic cavity through the drainage lumen of the axially elongate tube (Col. 12, lines 60-67); and removing the guidewire 15 after inserting the axially elongate tube 112, as the guidewire 15 is only intended as placement guide to be removed once apparatus 10 is placed.

With respect to **claim 22:** The method taught by Balbierz further comprises the step of selectively bending a region of increased flexibility near the distal tip of the axially elongate tube 112 while advancing the tube into the chest cavity. (Col. 10, lines 52-59)

With respect to **claim 23:** The axially elongate tube 112 further comprises a sideport 24', operably connected to the drainage lumen 113, wherein said sideport 24' is located near the distal end of the axially elongate tube. (Fig. 2, Col. 8, lines 32-35)

With respect to **claim 25:** The valve 32 is pre-attached to the axially elongate tube 112 near the proximal end of the axially elongate tube 112, prior to removal of the axially elongate tube from a package. (Fig. 8, Col. 12, lines 55-59)

With respect to **claim 27:** The method taught by Balbierz further comprises the step of advancing an extracorporeal fixation device 52 distally along the axially elongate tube 112 so that the extracorporeal fixation device 52 is adjacent the thoracic wall of the patient and then locking the extracorporeal fixation device 52 to prevent axial movement of the extracorporeal fixation device along the axially elongate tube 112 by winding the spring 52 such that it fits in the tube 112 but recovers its initial diameter upon delivery, thus holding itself in place within said tube 112. (Col. 19, lines 1-28)

With respect to **claim 29:** The method taught by Balbierz further comprises the step of activating an intracorporeal fixation device, said intracorporeal fixation device being affixed to the axially elongate tube 112. (Col. 19, lines 41-44)

With respect to **claim 30:** The step of activating the intracorporeal fixation device comprises inflating a balloon through a gas supply port 24' capable of functioning as a balloon inflation port located substantially near the proximal end of the axially elongate tube 112. (Col. 8, lines 31-35, Col. 19, lines 41-44)

With respect to **claim 31:** The step of selectively opening the valve comprises drawing a vacuum within the valve enabling lumen 113 via port 24' (Col. 8, lines 35,36), said valve enabling lumen 113 being operably separated and not connected to the drainage lumen of the valve, to open the valve. Balbierz teaches multiple lumens 113 coupled to port 24' (Col. 8, lines 32-35), therefore the valve enabling lumen and drainage lumen are not connected.

With respect to **claim 33:** The valve 32 is a normally closed valve, because the valve is positive or negative pressure operated, which would require an external positive or negative pressure source attached to port 24' at all times, which is not the case.

With respect to **claim 34:** Balbierz teaches a method of draining of fluid, air and contaminants from a thoracic cavity of a mammalian patient comprising: inserting a chest drainage apparatus into a thoracic cavity of a mammalian patient, wherein the chest drainage apparatus comprises an axially elongate tube 112 with a pre-inserted flexible trocar 12 having a tapered distal tip 16', further wherein the flexible trocar 12 is pre-inserted through a non-removable, pressure-operated, bidirectional valve 32, attached to a proximal end of the axially elongate tube 112, and through a drainage lumen of the axially elongate tube and extends substantially the length of the axially elongate tube; advancing the chest drainage apparatus to its target location 5' within the thoracic cavity; removing the flexible trocar 12 from the drainage lumen of the valve 32 and the axially elongate tube 112; and selectively opening or closing the valve 32 to control influx and efflux of fluid, air or contaminants into the thoracic cavity through the drainage lumen of the axially elongate tube. (Col. 8, lines 32-36, Col. 12, lines 60-67)

With respect to **claim 35:** The method taught by Balbierz further comprises the step of activating an intracorporeal fixation device, said intracorporeal fixation device being affixed to the axially elongate tube 112. (Col. 19, lines 41-44)

With respect to **claim 36:** The method taught by Balbierz further comprises the step of activating an internal fixation device, said internal fixation device comprising a balloon which is pre-attached to the axially elongate tube 112, the activation step being accomplished by

application of fluid pressure via port 24' at the proximal end of the axially elongate tube 112, said fluid pressure causing inflation of the balloon. (Col. 8, lines 31-35, Col. 19, lines 41-44)

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz ('070) in view of Nissenbaum et al (U.S. Patent No. 6,669,708).

With respect to **claim 12:** Balbierz teaches that axially elongate tube 112 is comprised of shape memory material and teaches piezoelectric materials as actuators 25' for steering tube 112, but does not teach that said bending or steering of said axially elongate tube is caused by electrical activation of a plurality of shape-memory actuators acting in opposition, wherein one actuator is enabled simultaneously with the opposing actuators not being activated. Nissenbaum teaches a flexible introducer device comprising a flexible tube, wherein bending of the tube is performed by electrically actuating shape memory alloy materials (shape memory actuator) formed as part of the introducer device. This electrical actuation can be targeted, wherein one actuator is enabled simultaneously with the opposing actuators not being activated. These materials are actuated by application of current (electrical activation) to permit bending of the flexible tube portion. Nissenbaum teaches that the use of these materials to create flexible products is known in the art ('708, Col. 22, lines 9-23), and the method of electrical activation to allow bending taught by Nissenbaum constitutes an alternate method to the method of bending taught by Balbierz using similar materials, therefore it would be obvious to one of ordinary skill in the art to

modify the device taught by Balbierz so as to allow steering by means of actuators acting in opposition, wherein one actuator is enabled simultaneously with the opposing actuators not being activated as taught by Nissenbaum to allow selective steering of the axially elongate tube.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz in view of de la Torre et al (U.S. Patent No. 6,319,246).

With respect to **claim 32:** The step of selectively closing the valve comprises removing a vacuum from within a valve enabling lumen 113 by detaching the vacuum from port 24' (Col. 8, lines 32-36).

Balbierz does not teach an open celled foam that expands to close the valve. De la Torre teaches a laparoscopic device access port wherein the device has a valve that comprises an open celled foam that expands to close the valve. De la Torre teaches that other valve structures may also be employed. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

January 24, 2007

TATYANA ZALUKAEVA
PRIMARY EXAMINER